FDA 510(k) Premarket Notification

K151686 HumanPen Ergo II

CLEARED

Dec 30, 2015
190 days to decision

K151686 · Product code: **FMF** · General Hospital
Source: https://www.510kdatabase.net/k151686/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Jun 23, 2015
Decision date	Dec 30, 2015
Days to decision	190 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Eli Lilly and Company, Inc.**
Location	Indianapolis, IN, US
Contact	CHRISTINE A. PHILLIPS
510(k) history	2 submissions · 2 cleared · 2015-2016